IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FRESENIUS MEDICAL CARE HOLDINGS, INC.	)	
Plaintiff,	)	Civ. Action No. 10-cv-11429 (RGS) (LTS)
v.	)	
AMNEAL PHARMACEUTICALS, LLC,	)	
Defendant.	)	

DEFENDANT AMNEAL PHARMACEUTICALS, LLC'S
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant-Counterclaim Plaintiff Amneal Pharmaceuticals, LLC ("Amneal") for its Answer, Affirmative Defenses, and Counterclaims to the Complaint of Plaintiff-Counterclaim Defendant Fresenius Medical Care Holdings, Inc. ("Fresenius"), alleges as follows:

THE PARTIES

1. Amneal is without knowledge or information sufficient to form a belief as to the allegations of paragraph 1, and on that basis denies said allegations.

2. Admits that it is a limited liability company organized under the laws of Delaware and that it has its principal place of business at 209 McLean Boulevard, Paterson, New Jersey 07504.

NATURE OF ACTION

3. Amneal admits that it submitted Abbreviated New Drug Application ("ANDA") No. 20-1658 to the Food and Drug Administration ("FDA") for approval to market a generic calcium acetate product. Amneal denies any remaining allegations and legal conclusions in

paragraph 3 and specifically denies that this action states a proper claim for patent infringement or injunctive relief.

JURISDICTION AND VENUE

4. Amneal admits that ANDA No. 20-1658 contains a certification under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") of the Drug Price Competition and Patent Term Restoration Act of 1984. Amneal denies any remaining allegations and legal conclusions contained in paragraph 4 and specifically denies that it has or will infringe any claim of U.S. Patent No. 6,576,665 ("the '665 patent").

5. Paragraph 5 contains conclusions of law to which no response is required. Amneal will not contest personal jurisdiction for purposes of this action only.

6. Paragraph 6 contains conclusions of law to which no response is required. Amneal will not contest venue for purposes of this action only.

THE '665 PATENT

7. Amneal admits that what appears to be a copy of the '665 patent was attached to the Complaint as Exhibit A. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 7, and on that basis denies those allegations.

8. Amneal admits that ANDA No. 20-1658 contains a Paragraph IV certification. Amneal denies any remaining allegations and legal conclusions contained in paragraph 8 and specifically denies that it has or will infringe any claim of the '665 patent.

9. Amneal admits that it sent a letter dated July 1, 2010, under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) notifying Fresenius of Amneal's submission to the FDA of ANDA No. 20-1658 containing a Paragraph IV certification which speaks for itself.

Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 9, and on that basis denies those allegations.

10. Amneal denies the allegations in paragraph 10.

11. Amneal denies the allegations in paragraph 11.

12. Amneal is without knowledge or information sufficient to form a belief as to the allegations of paragraph 12, and on that basis denies said allegations.

13. Amneal denies the allegations in paragraph 13 and specifically denies that it has or will infringe any claim of the '665 patent.

14. Amneal denies the allegations in paragraph 14 and specifically denies that it has or will infringe any claim of the '665 patent.

THE '445 PATENT

15. Amneal denies the allegations in paragraph 15.

16. Amneal admits that what appears to be a copy of U.S. Patent No. 6,875,445 ("the '445 patent") was attached to the Complaint as Exhibit B. Amneal denies that it has or will infringe any claim of the '445 patent. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 16, and on that basis denies said allegations.

17. Amneal admits that there is a justiciable controversy between Amneal and Fresenius as to the '445 patent. Amneal denies the remaining allegations in paragraph 17 and specifically denies that it has or will infringe any claim of the '445 patent.

18. Amneal denies the allegations in paragraph 18.

PRAYER FOR RELIEF

Amneal denies that Fresenius is entitled to any judgment or relief against Amneal and, therefore, specifically denies paragraphs (a) through (g) of Fresenius' Prayer For Relief.

AFFIRMATIVE DEFENSES

First Affirmative Defense (Non-Infringement)

19. Amneal's proposed calcium acetate product, as described in ANDA No. 20-1658, has not infringed, does not infringe, and will not infringe, either directly or indirectly, any claim of the '665 patent, either literally or under the doctrine of equivalents.

20. Amneal's proposed calcium acetate product, as described in ANDA No. 20-1658, has not infringed, does not infringe, and will not infringe, either directly or indirectly, any claim of the '445 patent, either literally or under the doctrine of equivalents.

Second Affirmative Defense (Patent Invalidity)

21. Each claim of the '665 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

22. Each claim of the '445 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

Third Affirmative Defense (Patent Unenforceability - Inequitable Conduct)

23. The claims of the '665 patent are unenforceable on the grounds of inequitable conduct. As set forth in Count III of Amneal's Counterclaims *infra*, Fresenius, its predecessors, and their representatives (collectively, "applicants") withheld, concealed, or mischaracterized

information material to patentability, of which they were aware, with an intent to deceive the United States Patent and Trademark Office ("PTO") during the prosecution of the '665 patent. Amneal incorporates by reference the allegations in Count III of its Counterclaims as if fully stated herein.

24. The claims of the '445 patent are unenforceable on the grounds of inequitable conduct. As set forth in Count III of Amneal's Counterclaims *infra*, Fresenius, its predecessors, and their representatives (collectively, "applicants") withheld, concealed, or mischaracterized information material to patentability, of which they were aware, with an intent to deceive the United States Patent and Trademark Office ("PTO") during the prosecution of the '445 patent. Amneal incorporates by reference the allegations in Count III of its Counterclaims as if fully stated herein.

Fourth Affirmative Defense
(Patent Misuse)

25. The claims of the '665 patent are void and unenforceable on the grounds of patent misuse. Amneal incorporates by reference the allegations in Count III of its Counterclaims as if fully stated herein.

26. The claims of the '445 patent are void and unenforceable on the grounds of patent misuse. Amneal incorporates by reference the allegations in Count III of its Counterclaims as if fully stated herein.

Fifth Affirmative Defense
(Unclean Hands)

27. Fresenius' claims and requested relief with respect to the '665 patent are barred by the doctrine of unclean hands. Amneal incorporates by reference the allegations in Count III of its Counterclaims as if fully stated herein.

28. Fresenius' claims and requested relief with respect to the '445 patent are barred by the doctrine of unclean hands. Amneal incorporates by reference the allegations in Count III of its Counterclaims as if fully stated herein.

Sixth Affirmative Defense
(Failure to State a Claim)

29. Fresenius' Complaint fails to state a claim upon which relief can be granted.

Reservation of Rights

30. Amneal reserves the right to assert such other defenses that may appear as discovery proceeds in this case.

DECLARATORY JUDGMENT COUNTERCLAIMS

Counterclaim Plaintiff Amneal Pharmaceuticals, LLC ("Amneal") for its counterclaims against Fresenius Medical Care Holdings, Inc. ("Fresenius") alleges as follows:

The Parties

1. Amneal is a limited liability company organized under the laws of Delaware having its principal place of business at 209 McLean Boulevard, Paterson, New Jersey 07504.

2. On information and belief, Fresenius is a New York corporation having its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

Jurisdiction and Venue

3. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, under the United States Patent Laws, 35 U.S.C. § 1 *et seq.*, and under 21 U.S.C. § 355(j)(5)(C).

4. This Court has subject-matter jurisdiction based on 28 U.S.C. §§ 1331 and 1338(a), 2201 and 2202, and 21 U.S.C. § 355(j)(5)(C).

5. This Court has personal jurisdiction over Fresenius because Fresenius resides in and is doing business within this District, and because Fresenius consented to jurisdiction by suing Amneal in this District.

6. This Court is the proper venue under 28 U.S.C. §§ 1391, 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II).

Background

7. This is an action for declaratory relief seeking a declaration of noninfringement, invalidity and unenforceability of United States Patent Nos. 6,576,665 ("the '665 patent") and 6,875,445 ("the '445 patent") (collectively, "the patents-in-suit").

8. As set forth below, Amneal submitted ANDA No. 20-1658, containing a certification regarding the '665 patent under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") of the Drug Price Competition and Patent Term Restoration Act of 1984, to the FDA seeking approval to market a generic calcium acetate product.

9. Fresenius filed the instant Complaint in this Court alleging that Amneal's act of submitting ANDA No. 20-1658 infringes the '665 patent and that Amneal's intended commercial manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 20-1658 will infringe the '445 patent.

10. Fresenius and Nabi Biopharmaceuticals ("Nabi"), the company from which Fresenius acquired the rights to PhosLo® (calcium acetate) Gelcaps, previously asserted the patents-in-suit against Roxane Laboratories, Inc. ("Roxane") over its ANDA for generic calcium acetate capsules in another court. *See Nabi Biopharmaceuticals v. Roxane Laboratories, Inc.*, 2:05-cv-00889 (S.D. Oh. 2005).

11. Fresenius also asserted the patents-in-suit against Paddock Laboratories, Inc. over its ANDA for generic calcium acetate capsules in this Court. *See FMCH v. Paddock Laboratories, Inc.*, 1:09-cv-11130 (D. Mass. 2009) (RGS).

12. Based on Fresenius' filing of the instant Complaint against Amneal asserting infringement of the patents-in-suit, and Amneal's denial thereof, as well as Fresenius' prior history of asserting the patents-in-suit against other ANDA applicants for calcium acetate capsules, an actual controversy now exists between Amneal and Fresenius as to whether Amneal infringes any valid and enforceable claim of the patents-in-suit.

13. Unless it is enjoined, Fresenius will continue to assert that Amneal infringes the patents-in-suit and will continue to impair Amneal's ability to market its generic calcium acetate capsules, causing irreparable harm to Amneal's business.

A. The Patents-In-Suit

14. The face of the '665 patent, titled "Encapsulated Calcium Acetate Caplet and a Method of Inhibiting Gastrointestinal Phosphorous Absorption," indicates that it issued on June 10, 2003, from Application No. 09/824,949 ("the '949 application") filed on April 3, 2001.

15. The face of the '665 patent lists Edmund Dennett, Jr., Robert M. Raleigh, Jr. and Bruce H. Aronson as the inventors.

16. The face of the '445 patent, titled "Encapsulated Calcium Acetate Caplet and a Method of Inhibiting Gastrointestinal Phosphorous Absorption," indicates that it issued on April 5, 2005, from Application No. 10/279,598 ("the '598 application"), filed on October 24, 2002. The '598 application purports to be a continuation application of the '949 application from which the '665 patent issued.

17. The face of the '445 patent lists Edmund Dennett, Jr., Robert M. Raleigh, Jr. and Bruce H. Aronson as the inventors.

B. History of Fresenius' NDA for PhosLo® Capsules

18. On information and belief, Fresenius purports to be the present approval holder of New Drug Application ("NDA") No. 21-160 for PhosLo® (calcium acetate) Gelcaps.

19. PhosLo® Gelcaps is the trademark under which Fresenius markets calcium acetate capsules for the treatment of hyperphosphatemia, a condition in patients with end stage renal failure.

20. Braintree was the original sponsor of NDA No. 21-160 pursuant to an application submitted to the FDA on or about September 29, 2000. The FDA approved NDA No. 21-160 for PhosLo® Gelcaps on or about April 2, 2001.

21. Before seeking approval to market a *capsule* formulation of calcium acetate, Braintree marketed and sold a *tablet* version, also under the trademark PhosLo®, under NDA No. 19-976, which was approved by the FDA as early as December 10, 1990.

22. On information and belief, PhosLo® *tablets* were discontinued at some point following FDA approval of NDA No. 21-160 for PhosLo® Gelcaps.

23. On information and belief, PhosLo® *tablets* were marketed and sold by Braintree in the United States more than one year prior to April 3, 2001, the date of filing for the '949 application to which both the '665 and '445 patents claim priority.

24. Under 21 U.S.C. § 355(b)(1)(G), an NDA holder must provide to the FDA the patent number and expiration date of any patent(s) that it believes "claims the drug for which the applicant submitted the application or which claims a method of using such drug." The FDA

publishes these patent(s) in an electronic, publicly available database called APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, also known as the "Orange Book."

25. Braintree requested that FDA list the '665 patent in the Orange Book in connection with PhosLo® Gelcaps because it believed that the '665 patent claims cover PhosLo® Gelcaps themselves or methods of using PhosLo® Gelcaps.

26. Fresenius, after acquiring NDA No. 21-160 for PhosLo® Gelcaps, has maintained the listing of the '665 patent in the Orange Book.

27. On information and belief, neither Braintree, Nabi, nor Fresenius requested that the FDA list the '445 patent - the other patent asserted in this action - in the Orange Book for PhosLo® Gelcaps.

28. In seeking approval from the FDA to market PhosLo® Gelcaps, Braintree referenced the safety and efficacy data for by PhosLo® *tablets* marked under NDA No. 19-976.

29. In seeking approval from the FDA to market PhosLo® Gelcaps, Braintree represented to the FDA that its proposed PhosLo® Gelcaps were bioequivalent to its PhosLo® *tablets* marked under NDA No. 19-976.

30. In seeking approval from the FDA to market PhosLo® Gelcaps, Braintree submitted to the FDA data from dissolution studies that demonstrated the comparable dissolution characteristics of its proposed PhosLo® Gelcaps and PhosLo® *tablets*.

31. In reviewing Braintree's application for PhosLo® Gelcaps, the FDA stated that "comparative dissolution data for the caplet and tablet were submitted but these data were generated with Apparatus II (paddles) at **100rpm**. Although all other conditions were acceptable, the sponsor was asked to generate dissolution data in the same 5 media [water, 0.1N HCl, pH 4.5 buffer, pH 6.8 buffer and pH 7.5 buffer] using a paddle speed of **50rpm**." The FDA

then concluded "[t]he caplet formulation demonstrates comparable dissolution to the approved tablet formulation." NDA No. 21-160, Clinical Pharmacology and Biopharmaceutics Review(s) at pg. 1 of 9.[1]

32. In seeking approval from the FDA to market PhosLo® Gelcaps, Braintree told the FDA during the FDA-approval process for PhosLo® Gelcaps that the caplet dose form inserted into a gelatin capsule "has the exact ***same formulation*** and ***weight of calcium acetate*** as the original PhosLo® tablet." *Id.* at unnumbered page (emphasis added).

33. In seeking approval from the FDA to market PhosLo® Gelcaps, Braintree submitted a supplement to NDA No. 19-976 for PhosLo® *tablets*, and did not submit a separate NDA for PhosLo® Gelcaps, because Braintree believed its proposed PhosLo® Gelcaps formulation to be sufficiently similar to the then marketed PhosLo® *tablets* formulation.

34. In reviewing Braintree's application for PhosLo® Gelcaps, the FDA stated that "[s]ince these drug products have the same formulation as the previously approved PhosLo® Tablets (NDA 19-976), this NDA was originally filed as a supplement to NDA 19-976." NDA No. 21-160, Chemistry Review(s) at 2.[2]

C. Amneal's ANDA for Calcium Acetate Capsules

35. Amneal submitted ANDA No. 20-1658 to the FDA seeking permission to market calcium acetate capsules ("Amneal's product"), a generic version of PhosLo® Gelcaps.

36. Amneal's ANDA No. 20-1658 contained a Paragraph IV certification under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) requesting FDA approval

[1] (*available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/021160_Phoslo_biopharmr.pdf)

[2] (*available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/021160_Phoslo_chemr.pdf)

to engage in the commercial manufacture, use, sale, offer for sale or importation of Amneal's product in the United States prior to the expiration of the '665 patent.

37. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Amneal provided notice of its Paragraph IV certification to Fresenius in a letter dated July 1, 2010 ("Notice Letter"), which was received by Fresenius on or before July 6, 2010.

38. On August 24, 2010, Fresenius sent a letter to the FDA asserting that its August 19, 2010, infringement action triggered the 30-month statutory stay before Amneal's ANDA No. 20-1658 may be approved under 35 U.S.C. § 355(j)(5)(B)(iii).

39. The present suit by Fresenius, by virtue of the automatic 30-month stay, impairs Amneal's ability to obtain approval of its ANDA No. 20-1658 and market its calcium acetate capsule product.

COUNT I
Declaratory Judgment of Non-Infringement

40. Amneal incorporates paragraphs 1-39 of the Counterclaims as if fully set forth herein.

41. Amneal's proposed calcium acetate product, as described in ANDA No. 20-1658, has not infringed, does not infringe, and will not infringe, either directly or indirectly, any claim of the '665 patent, either literally or under the doctrine of equivalents.

42. Amneal's proposed calcium acetate product, as described in ANDA No. 20-1658, has not infringed, does not infringe, and will not infringe, either directly or indirectly, any claim of the '445 patent, either literally or under the doctrine of equivalents.

43. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., Amneal requests a declaration from the Court that Amneal does not infringe the claims of the asserted patents.

COUNT II
Declaratory Judgment of Patent Invalidity

44. Amneal incorporates paragraphs 1-43 of the Counterclaims as if fully set forth herein.

45. Each claim of the '665 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

46. Each claim of the '445 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

47. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the claims of the asserted patents are invalid.

COUNT III
Declaratory Judgment of Unenforceability
Due to Inequitable Conduct

48. Amneal incorporates paragraphs 1-47 of the Counterclaims as if fully set forth herein.

A. Unenforceability of The '665 Patent

49. All patent applicants, their attorneys, and those substantively involved in the prosecution owe a "duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability." *See* 37 C.F.R. § 1.56.

50. "The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned." *Id.*

51. Information is material to patentability when "[i]t refutes, or is inconsistent with, a position the applicant takes in: [o]pposing an argument of unpatentability relied on by the [PTO], or [a]sserting an argument of patentability." *Id.*

52. Information is also material to patentability when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.

53. Braintree, through the inventors of the '665 patent, its attorneys and/or those substantively involved in the prosecution of the application that issued as the '665 patent breached their duty of candor and good faith by making affirmative misrepresentations of material facts or omitting material information with the specific intent to deceive the PTO during prosecution of the '949 application

54. On information and belief, Robert M. Raleigh, Jr., one of the named inventors on the '665 patent, was an employee at Braintree at the time of filing and prosecution of the '949 application. Mr. Raleigh was substantively involved in the preparation or prosecution of the '949 application before the PTO and, thus, owed a "duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the [PTO] all information known to [him] to be material to patentability" of the '665 patent.

55. On information and belief, Mark Cleveland, Ph.D., was the Vice-President of New Product Development at Braintree while the '949 application was pending before the PTO. Dr. Cleveland was in direct and frequent contact with Braintree's patent counsel, and substantively involved in the preparation or prosecution of the '949 application. Dr. Cleveland owed a "duty of candor and good faith in dealing with the [PTO], which includes a duty to

disclose to the [PTO] all information known to [him] to be material to patentability" of the '665 patent.

56. At the time of preparation and during prosecution of the application that issued as the '665 patent, Mr. Raleigh, Dr. Cleveland, and other employees at Braintree knew or should have known that Braintree had marketed and sold PhosLo® *tablets* with the same or substantially same formulation, *e.g.*, same or substantially same bulk density or comparable dissolution profile, purportedly claimed by the '665 patent, more than one year prior to the filing of the '949 application

57. Braintree's marketing or sale of PhosLo® *tablets* more than one year prior to the filing of the '949 application was material to patentability of the '665 patent.

58. During prosecution of the '949 application, the PTO sent a first Office action rejecting all pending claims as unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 4,870,105 to John S. Fordtran ("Fordtran"). The Office action stated: "[b]ased on the teachings of Fordtran, compositions of calcium acetate for inhibiting gastrointestinal absorption of phosphorus and methods for using the compositions would have been known to one with ordinary skill in the art."

59. In attempting to overcome this rejection, Braintree argued that the prior art should be distinguished based on the recited bulk density of calcium acetate in the '665 patent.

60. During prosecution of the '949 application, applicants also attempted to distinguish the prior art on the basis of dissolution.

61. During the prosecution of the '949 application, in the last amendment prior to allowance, applicants amended the claims to include the dissolution recited in the issued '665 patent.

62. In a January 28, 2002, Response to this Office Action, Braintree summarized a January 18, 2002, telephone interview with PTO Examiners Robert W. DeWitty and Jose Dees. In particular, Braintree wrote:

> Applicants were advised [by Examiners] that the pending claims would be deemed patentable provided that it can be demonstrated that neither the art cited in the Office Action, ***nor any other art that applicants are aware of***, discloses the formulation of calcium acetate compositions based upon the bulk density of calcium acetate as a raw material, or a range of bulk density of calcium acetate which enables the formulation of calcium acetate compositions that is compressible to form a caplet which optimally fits within a capsule and retains its optimal pharmaceutical properties.

(emphasis added).

63. In the same January 28, 2002, Response, Braintree submitted a supplemental Information Disclosure Statement ("IDS") with a list of new references it uncovered during a supplemental review and search of prior art pursuant to the Examiners' instructions during the January 18, 2002 interview.

64. Notably, the supplemental IDS filed by Braintree did not include any information about Braintree's marketing of PhosLo® *tablets* more than one year prior to the filing of the '949 application, even though Braintree was aware of their existence and even though Braintree had represented to the FDA that PhosLo® Gelcaps, which purportedly are claimed by the '665 patent, "have the same formulation as the previously approved PhosLo® *tablets*." (emphasis added).

65. By this omission, Braintree withheld from the examiner that it marketed calcium acetate tablets that met nearly all, if not all, of the limitations of the composition purportedly claimed in the '665 patent, including the same bulk density and comparable dissolution profile, for more than a decade prior to the filing of the '949 application.

66. Braintree's failure to disclose information regarding its marketing of PhosLo® *tablets* more than one year prior to the filing of the '949 application was a false and deliberate omission or misrepresentation of a material fact that was intended to deceive the PTO into granting the '665 patent.

67. The Examiner and the PTO relied upon these omissions and misrepresentations by Braintree in allowing the '665 patent to issue.

68. Accordingly, at least for the foregoing reasons, the '665 patent is unenforceable due to inequitable conduct by the inventors and the prosecuting attorneys, or other persons at Braintree substantively involved in the preparation or prosecution of the '949 application that matured into the '665 patent.

B. Unenforceability of the '445 Patent

69. Amneal incorporates paragraphs 1-68 of the Counterclaims as if fully set forth herein.

70. A finding of inequitable conduct with regard to an earlier patent application may render the claims of a later related patent unenforceable. *See Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007).

71. The '445 patent is related to the '665 patent and is unenforceable due to the unenforceability of the '665 patent.

72. The '445 patent is also unenforceable based on separate and independent inequitable conduct by Braintree during prosecution of the '598 application from which the '445 patent issued. On information and belief, Braintree made affirmative misrepresentations of material facts or omitted material information with the specific intent to deceive the PTO during prosecution of the '598 application.

73. At the time of preparation and during prosecution of the '598 application, Mr. Raleigh, Dr. Cleveland, and other employees at Braintree knew or should have known that Braintree had marketed and sold PhosLo® *tablets* with the same or substantially same formulation, *e.g.*, same or substantially same bulk density or comparable dissolution profile, purportedly claimed by the '445 patent, more than one year prior to the filing of the '949 application.

74. Braintree's marketing or sale of PhosLo® *tablets* more than one year prior to the filing of the '949 application was material to patentability of the '445 patent.

75. During prosecution of the '598 application, Braintree represented to the PTO that the claims of the '598 application are patentable over the prior art based on the recited bulk densities of calcium acetate.

76. In the Notice of Allowability of the '445 patent, the Examiner distinguished the prior art because "unlike the instant claims, the prior [art] does not disclose the specific bulk densities and amounts of calcium acetate compressed to yield uptimum [sic] inner volume dimensions of capsule."

77. On information and belief, the Examiner and PTO allowed the claims of the '445 patent relying on Braintree's misrepresentations concerning the recited bulk densities of calcium acetate.

78. On information and belief, the Examiner and PTO allowed at least claims 6, 13-17, 23, and 30-34 of the '445 patent because of applicant's amendments concerning dissolution.

79. During prosecution of the '598 application, Braintree did not disclose to the Examiner information about Braintree's marketing or sale of PhosLo® *tablets* more than one year prior to the filing of the '949 application, even though Braintree was aware of their existence and

even though Braintree had represented to the FDA that PhosLo® Gelcaps have the same formulation as the previously approved PhosLo® *tablets*.

80. By this omission, Braintree withheld from the Examiner that its marketed calcium acetate tablets met nearly all, if not all, of the limitations of the composition purportedly claimed in the '445 patent, including the same bulk density and comparable dissolution profile, for more than a decade prior to the filing of the '949 application.

81. Braintree's failure to disclose information regarding its marketing of PhosLo® *tablets* more than one year prior to the filing of the '949 application was an intentional omission or misrepresentation of a material fact that intended to deceive the PTO into granting the '445 patent.

82. The Examiner and the PTO were deceived by these omissions or misrepresentations by Braintree.

83. Accordingly, at least for the foregoing reasons, the '445 patent is unenforceable due to inequitable conduct by the inventors and the prosecuting attorneys, or other persons at Braintree substantively involved in the preparation or prosecution of the '949 and '598 applications that matured into the '445 patent.

PRAYER FOR RELIEF

WHEREFORE, Amneal respectfully requests judgment and relief in its favor against Counterclaim Defendant Fresenius as follows:

A. Dismissing Fresenius' Complaint with prejudice and denying each and every prayer for relief contained therein;

B. Declaring that the commercial manufacture, use, sale, offer for sale, marketing, or importation of the calcium acetate product described in ANDA No. 20-1658 does not and will not infringe any claim of the '665 and '445 patents;

C. Declaring that the claims of the '665 and '445 patents are invalid;

D. Declaring that the claims of the '665 and '445 patents are unenforceable;

E. Enjoining Fresenius, its officers, employees, agents, representatives, attorneys and others acting on its behalf, from threatening or initiating infringement litigation against Amneal or its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Amneal, or charging them either orally or in writing with infringement of any patent asserted against Amneal;

F. Declaring that this is an exceptional case, and that Amneal be awarded its attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

G. Awarding to Amneal such further relief as this Court may deem necessary, just and proper.

Dated: September 10, 2010

Respectfully submitted,

/s/ *Edward J. Naughton*

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CERTIFICATE OF SERVICE

This is to certify that on this 10th day of September 2010, a true and correct copy of DEFENDANT AMNEAL PHARMACEUTICALS, LLC'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS was caused to be served by ECF and electronic mail on the following counsel of record:

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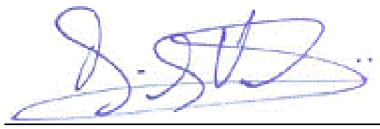
Dated: September 10, 2010



Dennies Varughese